IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARBOR PHARMACEUTICALS, LLC and TAKEDA PHARMACEUTICAL COMPANY LIMITED,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
SABA ILAC SANAYI VE TICARET AS,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Arbor Pharmaceuticals, LLC ("Arbor") and Takeda Pharmaceutical Company Limited ("Takeda) (collectively, "Plaintiffs"), for their Complaint against Defendant Saba Ilac Sanayi ve Ticaret AS ("Saba" or "Defendant"), hereby allege as follows:

THE PARTIES

1. Arbor is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 6 Concourse Parkway, Suite 1800, Atlanta, GA 30328.

2. Takeda is a corporation organized and existing under the laws of Japan, having a principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka, Japan.

3. Upon information and belief, Saba is a corporation organized and existing under the laws of Turkey, having a principal place of business at Merkez Mah. Basin Ekspres Cad. No: 1, Kucukcekmece, Istanbul, Turkey, 34303. Upon information and belief, Saba plans to develop, manufacture, market, sell, distribute and/or import generic pharmaceutical versions of branded products throughout the United States, including in this Judicial District.

NATURE OF THE ACTION

4. This is a civil action for infringement of United States Patent Nos. 7,157,584 ("the '584 patent"), 7,572,920 ("the '920 patent"), and 9,066,936 ("the '936 patent") (collectively "the patents-in-suit"). This action arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*

JURISDICTION & VENUE

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Defendant at least because Defendant intends to market, sell, and/or distribute generic pharmaceutical drug products within this State and to residents of this State, including the generic drug product that is the subject of Abbreviated New Drug Application ("ANDA") No. 216699. The marketing, sale, and/or distribution of the generic drug product that is the subject of ANDA No. 216699 will lead to foreseeable harm and injury to Plaintiffs in this State. This Court has personal jurisdiction over Defendant for the additional reasons set forth below and for other reasons that will be presented to the Court if jurisdiction is challenged.

7. This Court also has personal jurisdiction over Defendant by virtue of, *inter alia*, the fact that it has committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement that has led to and/or will lead to foreseeable harm and injury to Plaintiffs, including Arbor, a Delaware corporation.

8. Alternatively, should the Court find that the above facts do not establish personal jurisdiction over Saba in this action, this Court may exercise jurisdiction over Saba pursuant to Fed. R. Civ. P. 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Saba is a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) Saba

has sufficient contacts with the United States as a whole, including, but not limited to, submitting ANDA No. 216699 to the FDA with the intent to develop, manufacture, market, sell, distribute, and/or import the generic drug product that is the subject of ANDA No. 216699 throughout the United States, such that this Court's exercise of jurisdiction over Saba satisfies due process.

9. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400.

THE PATENTS-IN-SUIT

10. On January 2, 2007, the '584 patent, entitled "Benzimidazole derivative and use thereof" was duly and legally issued. A copy of the '584 patent is attached as Exhibit A.

11. Takeda owns the '584 patent. Arbor holds an exclusive license to the '584 patent in the United States.

12. On August 11, 2009, the '920 patent, entitled "Benzimidazole derivative and use as A II receptor antagonist" was duly and legally issued. A copy of the '920 patent is attached as Exhibit B.

13. Takeda owns the '920 patent. Arbor holds an exclusive license to the '920 patent in the United States.

14. On June 30, 2015, the '936 patent, entitled "Solid pharmaceutical composition comprising a benzimidazole-7-carboxylate derivative and a pH control agent" was duly and legally issued. A copy of the '936 patent is attached as Exhibit C.

15. Takeda owns the '936 patent. Arbor holds an exclusive license to the '936 patent in the United States.

ACTS GIVING RISE TO THIS ACTION

16. Arbor holds New Drug Application ("NDA") No. 200796 for oral tablets containing 40/80 mg of azilsartan medoxomil as the active ingredient. Arbor markets and sells these oral tablets in the United States under the brand name EDARBI®.

17. Pursuant to 21 U.S.C. § 355(b)(1), the patents-in-suit are listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") as covering EDARBI® or its use.

18. Upon information and belief, Saba submitted ANDA No. 216699 to the FDA under 21 U.S.C. § 355(j). Upon information and belief, Saba's ANDA No. 216699 seeks FDA approval to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of an oral tablet containing 40 mg or 80 mg of azilsartan medoxomil ("the Saba Generic Product") prior to the expiration of the patents-in-suit.

19. Upon information and belief, by filing ANDA No. 216699, Saba has certified to the FDA that the Saba Generic Product has the same active ingredient as EDARBI® and the same or substantially the same proposed labeling as EDARBI®.

20. Upon information and belief, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Saba certified in ANDA No. 216699 that the claims of the patents-in-suit are invalid, unenforceable, or would not be infringed by the commercial manufacture, use, sale, or offer for sale of the Saba Generic Product.

21. Plaintiffs received written notification of Saba ANDA No. 216699 and its accompanying § 505(j)(2)(A)(vii)(IV) certification by FedEx® Priority Overnight dated February 2, 2022 ("Saba's Notice Letter").

22. Saba's Notice letter contained an Offer of Confidential Access ("OCA") to certain confidential information regarding the Saba Generic Product. Plaintiffs sent Saba a proposed markup of the OCA in an attempt to reach agreement on the terms for confidential access, but Saba rejected Plaintiffs' proposal and did not provide a counterproposal. As of the filing of this Complaint, the parties have not been able to reach an agreement.

23. To date, Saba has not provided Plaintiffs with a copy of any portions of ANDA No. 216699 or any information regarding the Saba Generic Product, beyond the information set forth in Saba's Notice Letter.

24. The limited information relating to the Saba Generic Product that was provided in Saba's Notice Letter does not demonstrate that the Saba Generic Product, which Saba has asked the FDA to approve for sale in the U.S., will not fall within the scope of issued claims of the patents-in-suit.

25. This action was commenced within 45 days of Plaintiffs receiving Saba's Notice Letter.

COUNT I
INFRINGEMENT BY SABA OF U.S. PATENT NO. 7,157,584

26. Plaintiffs re-allege paragraphs 1-25 as if fully set forth herein.

27. Saba's submission of ANDA No. 216699 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constituted infringement of the '584 patent under 35 U.S.C. § 271(e)(2)(A).

28. Upon information and belief, the commercial manufacture, use, offer for sale, sale, or import of the Saba Generic Product—if approved by the FDA, prior to the expiration of the '584 patent, and for use in accordance with its proposed labeling—would infringe and/or induce and/or contribute to the infringement of the '584 patent.

29. Separate and apart from certain contentions regarding patent validity, Saba's Notice Letter does not identify any factual bases for, or any opinion of, noninfringement of the claims of the '584 patent.

30. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval or Saba's ANDA No. 216699 be a

date that is not earlier than the expiration of the '584 patent, or any later expiration of exclusivity for the '584 patent to which Plaintiffs are or become entitled.

31. Plaintiffs will be irreparably harmed by Saba's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

32. Upon information and belief, Defendant was aware of the existence of the '584 patent and was aware that the filing of ANDA No. 216699 and the certification with respect to the '584 patent constituted an act of infringement of that patent.

COUNT II
INFRINGEMENT BY SABA OF U.S. PATENT NO. 7,572,920

33. Plaintiffs re-allege paragraphs 1-32 as if fully set forth herein.

34. Saba's submission of ANDA No. 216699 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constituted infringement of the '920 patent under 35 U.S.C. § 271(e)(2)(A).

35. Upon information and belief, the commercial manufacture, use, offer for sale, sale, or import of the Saba Generic Product—if approved by the FDA, prior to the expiration of the '920 patent, and for use in accordance with its proposed labeling—would infringe and/or induce and/or contribute to the infringement of the '920 patent.

36. Separate and apart from certain contentions regarding patent validity, Saba's Notice Letter does not identify any factual bases for, or any opinion of, noninfringement of the claims of the '920 patent.

37. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval or Saba's ANDA No. 216699 be a date that is not earlier than the expiration of the '920 patent, or any later expiration of exclusivity for the '920 patent to which Plaintiffs are or become entitled.

38. Plaintiffs will be irreparably harmed by Saba's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

39. Upon information and belief, Defendant was aware of the existence of the '920 patent and was aware that the filing of ANDA No. 216699 and the certification with respect to the '920 patent constituted an act of infringement of that patent.

COUNT III
INFRINGEMENT BY SABA OF U.S. PATENT NO. 9,066,936

40. Plaintiffs re-allege paragraphs 1-39 as if fully set forth herein.

41. Saba's submission of ANDA No. 216699 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constituted infringement of the '936 patent under 35 U.S.C. § 271(e)(2)(A).

42. Upon information and belief, the commercial manufacture, use, offer for sale, sale, or import of the Saba Generic Product—if approved by the FDA, prior to the expiration of the '936 patent, and for use in accordance with its proposed labeling—would infringe and/or induce and/or contribute to the infringement of the '936 patent.

43. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval or Saba's ANDA No. 216699 be a date that is not earlier than the expiration of the '936 patent, or any later expiration of exclusivity for the '936 patent to which Plaintiffs are or become entitled.

44. Plaintiffs will be irreparably harmed by Saba's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

45. Upon information and belief, Defendant was aware of the existence of the '936 patent and was aware that the filing of ANDA No. 216699 and the certification with respect to the '936 patent constituted an act of infringement of that patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment that:

A. Saba has infringed one or more claims of the '584 patent;

B. Saba has infringed one or more claims of the '920 patent;

C. Saba has infringed one or more claims of the '936 patent;

D. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any FDA approval of Saba's ANDA No. 216699 will not be earlier than the expiration date of the patents-in-suit, or any later expiration of any patent term extension or exclusivity for the patents-in-suit to which Plaintiffs are or become entitled;

E. Saba, its directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering to sell, selling, marketing, distributing, or importing the Saba Generic Product and any other product that infringes or induces or contributes to the infringement of one or more of the patents-in-suit, prior to the expiration of the patents-in-suit, including any exclusivities or extensions to which Plaintiffs are or become entitled;

F. Plaintiffs be awarded monetary relief to the extent Saba commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, any product that infringes or induces or contributes to the infringement of the patents-in-suit within the United States prior to the expiration of the patents-in-suit, including any later expiration of any patent term extensions or exclusivities for the patents-in-suit to which Plaintiffs are or will become entitled, and that any such monetary relief be awarded to Plaintiffs with prejudgment interest;

G. Plaintiffs be awarded the attorneys' fees, costs, and expenses that they incur in litigating this action; and

H. Plaintiffs be awarded such other and further relief as this Court deems just and proper.

Dated: March 18, 2022

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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